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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,207

06/30/2006

Michael A. Levy

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7590

10/09/2008

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

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SUITE 800

WASHINGTON, DC 20005

EXAMINER

ROBINSON, BINTA M

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

10/09/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/563,207	Applicant(s) LEVY, MICHAEL A.	
	Examiner BINTA M. ROBINSON	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) _ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Detailed Action

The 112, second paragraph rejection, parts A and B, , the 103 (a) rejections over Cauwenberg et. al., , Der Puy et. al., and the 112, first paragraph rejection lack of written description rejection on pages 5 to the top half of page 6, are withdrawn in light of applicant's amendment's remarks and declaration.

(old rejections)

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

C. In claim 9, line 2, page 14, and everywhere else throughout claim 10, the phrase "an amount necessary to change the color of said saponified solution from a darker color to a lighter color" is unclear because this amount is not specified at the claim.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in scope with

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these claims. “The factors to be considered [in making an enablement rejection] have been summarized as a) the quantity of experimentation necessary, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and the breadth of the claims”, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. In the present case, the important factors leading to a conclusion of undue experimentation are the absence of any working example where the structures of the diester used and the diacid produced – are specified – and the absence of any working example in which 2-(2-imidazolin-2-yl)nicotinic acids are produced and the absence of any working examples wherein oxidizing agents other than H₂O₂ are used.

c) There is no working example where the specific structure of the diester used in the reaction or the specific diacid produced are specified. See example I on page 12, line 9. Additionally, the claims are drawn to all oxidizing agents, yet the singular example in the specification only uses H₂O₂. There is no evidence that all other oxidizing agents work to produce a diacid with a 98.9% purity. Hence, applicants must show that all other oxidizing agents can be used to produce diacids to a great degree of purity, accordingly.

g) The state of the art is that it is not predictable whether all other oxidizing agents will behave similarly in removing in-situ impurities from a saponified solution of pyridine-2,3-dicarboxylic acid ester. Thus, in the absence of experimentation, one cannot predict if a particular oxidizing agent will purify a saponified solution of pyridine-2,3-dicarboxylic acid using the instant process steps. h) The breadth of the claims includes all oxidizing agents and in claims 1-14, 16-30, 33-47, any and all pyridine -2,3-dicarboxylic esters. Thus, the scope is broad.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

Response to Applicant's Remarks

Regarding part C of the 112, second paragraph rejection, applicants argue that their amendments have overcome this rejection. However, this is not so because "an amount necessary to change the color of said saponified solution from a

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darker color to a lighter color" is is not specified at the claim. Applicant's also traverse the 112, first paragraph rejection beginning in the middle of page 6 and continuing on to page 8 of the outstanding office action. However, the applicant only argues that there is no reasons to doubt that oxidizing agents would behave similarly to remove impurities from a saponified solution of pyridine-2,3-dicarboxylic acid ester and attaches a Rule 132 Declaration. However, the declaration only cites product yields for the use of the use of H₂O₂, but not for the use of Sodium hypochlorite or Calcium hypochlorite as oxidizing agents. Therefore, the alleged similar behavior of these H₂O₂ oxidizing agents for the hypohalite agents is not demonstrated by evidence in the specification. Additionally, the applicant does not address the argument in the rejection above that lack of enablement exists because of the absence of any working example where the structures of the diester used and the diacid produced – are specified – and the absence of any working example in which 2-(2-imidazolin-2-yl)nicotinic acids are produced.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Janet Andres can be reached on 571-272-0867.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

/Binta M Robinson/

Examiner, Art Unit 1625

/Janet L. Andres/

Supervisory Patent Examiner, Art Unit 1625